

REMARKS

Reconsideration and allowance are respectfully requested. Claims 3 and 8 have been amended to describe further that the particles are capable of biological bonding to the detectable material, but when unbound the particles do not affect detection of the detectable material. The claims are also amended to clarify further that the reaction product is retained in the catching section because its size prevents it from passing through that section. Support for the amendment is found in the specification at, for example, page 9, lines 22-24. Therefore, claims 3-8 are pending and are presently believed allowable for that reason alone.

The Examiner has rejected claims 3-7 under 35 U.S.C. § 112, second paragraph for indefiniteness. The Examiner found the description of the particles confusing. The claims have been amended to describe further the particles. Therefore, the rejection should be withdrawn.

Claims 3-8 stand rejected under 35 U.S.C. § 102 (b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Cole et al., U.S. Patent No. 5,141,850. The Examiner cites Cole et al., as disclosing a device and a method for the detection of the HCG which includes a series of zones on a test strip. The strip contains, a (1) capturable component which includes immunologically react bio-tinlated 2B2 antibody, (2) a second zone comprising the coupling product of the first immunologically reaction substance and gold-labeled 2G9 antibody, and (3) a third zone comprising a capturable component which is preferably conjugated to streptavidin conjugated to solid latex particles. The two antibodies sandwich with the HCG. The biotin of the 2B2


antibody reacts with the straptavin to capture the complex by a "binding-interaction". Col. 9, ll.14-20.

The rejection is respectfully traversed, and reconsideration is requested.

The present invention is directed to a detection apparatus and method which utilizes physical size, not chemical or biochemical interaction, to retain the detectable material/marked particle complex in the catching section. The size of these complexes is larger than the pore size of the catching section. Therefore, the complex can not pass through. The present invention does not depend upon or create the "bonding interaction" and does not which the component in the catching section that creates the "bonding interaction" of the cited prior art. Accordingly, Cole et al. cannot be relied upon to reject claims 3-8 as anticipated or obvious.

It is believed, for the foregoing reasons, that the claims warrant allowance, and such action is earnestly solicited.

Respectfully submitted,



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Docket No: M2047-3

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Kenji NARAHARA; Toshiyuki UEHARA

Serial No.: 09/325,214

Art Unit: 1641

Filed: June 31, 1999

Examiner: NGUYEN, BAO THUY L

For: **DETECTION APPARATUS AND METHOD FOR SAME**

MARK-UP COPY OF AMENDMENT PURSUANT TO § 1.121

IN THE CLAIMS:

Amend claims 3 and 8 as follows:

3. (Amended) A detection apparatus for detecting the presence of a detectable material in a sample comprising:

- a fluid application section contacting said sample;
- a reaction reagent section, having particles, which are capable of biologically bonding to said detectable materials but which do not affect detection, of said detectable material when not biologically bonded to said detectable material and marking elements movably contained therein, connected to said fluid application

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section such that said sample moves from said fluid application section to said reaction reagent section;

a porous carrier connected to said reaction reagent section such that said sample moves from said reaction reagent section to said porous carrier;

wherein a reaction product is formed from biological bonding of said detectable material bonding with both said marking elements and said particles when said detectable material is present in said sample to form a reaction product and

a catching section in said porous carrier made from a material having a pore size smaller than a size of said reaction product, such that chromatographic movement of said marking elements not bonded in said reaction product [to said particles via said detectable material] is permitted through said catching section and whereby chromatographic movement of said reaction product is restricted, whereby because of the size of said reaction product, thereby causing said reaction product to be retained by said catching section.

8. (Amended) A detection method for detecting the presence of a detectable material in a sample comprising:

contacting said sample with fluid application section;

chromatographically moving said sample through said fluid application section, a reaction reagent section, a porous carrier, and a catching section;

providing said reaction reagent section with particles which are capable of biologically bonding to said detectable materials but which do not affect detection, of

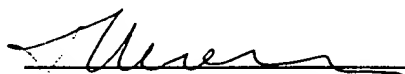
said detectable material when not biologically bonded to said detectable material and marking elements;

reacting said sample with said particles and said marking elements contained in said reaction reagent section to form a reaction product, such that said detectable material bonds with both said marking elements and said particles when said detectable material is present in said sample;

passing said sample, including any reaction product present, through a catching section, having a pore size smaller than a size of said reaction product and larger than a particle diameter of said marking elements whereby because of the size of said reaction product, thereby causing said reaction product to be retained in said catching section; and

analyzing presence of said marking elements at said catching section, whereby presence of said marking elements corresponds with presence of said detectable material.

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